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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/606,314	06/29/2000	Richard Fike	0942.4290005/RWE/BJD	1340

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EXAMINER	
FLOOD, MICHELE C	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 10/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/606,314	Fike et al.
Examiner	**Art Unit**
Michele Flood	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 17, 2003* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *27, 36, 39, 44-46, 70, 72, 92-95, and 103-105* is/are pending in the application.

4a) Of the above, claim(s) *27, 36, 39, 70, 72, 92-95, and 103-105* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☒ Claim(s) *44-46* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *21*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 26, 2003 has been entered.

Claims 27, 36, 39,44-46, 70, 72, 92-95 and 103-105 are under examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 27, 36, 39, 92-95 and 103 as amended and newly added Claims 104 and 105 remain/are rejected under 35 U.S.C. 102(b) as being anticipated by Peebles (A) and Getler et al. (N), as evidenced by the teachings of Ellington et al. (B), BBL Manual of Products and Laboratory Procedures (U), and Fassolitis et al. (V). Applicant's arguments have been considered, however, Applicant's amended claims do not distinguish over the prior art of record,

and for the reasons set forth below. Applicant claims an agglomerated eukaryotic cell culture medium powder prepared by agglomerating a dry powder eukaryotic cell culture medium with a solvent. Applicant further claims the medium powder of claims 27, wherein the agglomerated eukaryotic cell culture medium has a pH of between 7.1-7.5 when said medium is reconstituted with a solvent, wherein said solvent is water or serum. Applicant further claims an agglomerated eukaryotic cell culture medium subgroup powder prepared by agglomerating a dry powder eukaryotic cell culture medium subgroup with a solvent. Applicant further claims the medium powder of claim 27, wherein said medium powder exhibits reduced dusting and more rapid dissolution in comparison to a medium powder that is non-agglomerated. Applicant further claims the medium powder of any of claims 93-94, wherein the non-agglomerated medium powder is a lyophilized or ball-milled powder. Applicant further claims the agglomerated eukaryotic cell culture medium powder of claim 27, wherein said solvent is water, serum, aqueous acid or base. Applicant further claims the agglomerated eukaryotic cell culture medium subgroup powder of claim 39, wherein said solvent is water, serum, aqueous acid or base. Applicant further claims the agglomerated eukaryotic cell culture medium supplement powder of claim 44, wherein said solvent is water, serum, aqueous acid or base.

Applicant argues case law. Applicant also argues that neither Peebles nor Getler teach or suggest an agglomerated eukaryotic cell culture medium powder or medium subgroup powder. However, Applicant's arguments are not persuasive because the prior art teachings anticipate the claimed subject matter. Firstly, Peebles teaches a method of obtaining a dried milk powder, which

comprises lactose and milk protein, by agglomerating a spray-dried powder with water vapor and droplets of moisture. See Column 2, lines 13-70. The particulate matter of the dried milk powder taught by Peebles is of a size substantially greater than the particle size of the original powder, is readily dispersible in water, and has reduced dusting. See claims and Column 9, lines 46-54. Secondly, Getler teaches agglomerated milk products and milk-like products which are made in a two-stage agglomeration process comprising spray drying a pre-agglomerated concentrated premix by return of fine particles to an atomizer and, in a subsequent step, post-agglomeration by wetting and drying in a fluidized bed. The agglomerated dried products taught by Getler comprise the following ingredients: whey protein concentrates (see page 1, lines 11-14); and a fat component mixed with water, vitamins, and with raw materials in powder form, i.e., casein, whey, skim milk, malto dextrine, etc. (see page 6, line 36 to page 7, lines 1-2). In Example 3, Getler teaches an agglomerated medium powder which exhibits reduced dusting and rapid dissolution.

Applicant disagrees with the Office's interpretation of the phrases "agglomerated eukaryotic cell culture medium powder" and "agglomerated eukaryotic cell culture medium subgroup", as encompassing the powdered skim milk of Peebles and the powdered milk and milk-like products of Getler. Nonetheless, even as amended and given the broadest breadth of interpretation of the claims, the agglomerated powders taught by Peebles and Getler are still read as "agglomerated eukaryotic cell culture medium powder", "agglomerated eukaryotic cell culture medium supplement powder", and "agglomerated eukaryotic cell culture medium subgroup powder" because the products can be used in the culturing of cells (as evidenced by the teachings

of Ellington, BBL Manual of Products and Laboratory Procedures, and Fassolitis) and can be grouped within the scope of the various media subgroupings as described by Applicant on page 6, lines 13-28 and page 7.

Applicant's main argument is directed to the idea that the powdered skim milk of Peebles and the powdered milk and milk-like products of Getler fail to teach the claimed invention because "Dry powdered milk and milk products are not eukaryotic cell culture media powders of media subgroup powders." Applicant further argues that the present specification "explains that the powdered media and media subgroups of the invention, after being reconstituted in rehydrating solvent, can be used to cultivate cells." Applicant further explains that "Culture media and media subgroups contain a complex combination of nutrients, minerals and energy sources that support the cultivation of cells *in vitro*", and asserts that the dry powdered milk and milk products of the prior art when reconstituted are incapable of supporting the cultivation and/or growth of eukaryotic cells. However, Applicant's arguments are not found persuasive, especially when Applicant's arguments are not supported with any substantial evidence to the contrary. Although neither Peebles nor Getler expressly teach their dry powdered milk and milk products as either agglomerated eukaryotic cell culture medium or agglomerated eukaryotic cell culture medium subgroup powder, one of ordinary skill in the art of microbiology would indeed regard the prior art agglomerated powders as being capable of supporting the cultivation and/or growth of cells *in vitro*, when reconstituted, because it is notoriously old and well known in the art that milk and milk products contain the appropriate components to allow the cultivation of

eukaryotic cells (despite Ellington's seemingly lack of demonstration for the assertion that dry powdered skim milk or any dry powdered milk product can support the cultivation or growth of eukaryotic cells). For instance, on page 162, under "Skim Milk Powder", the BBL Manual of Products and Laboratory Procedures teaches a dehydrated skim milk powder, which "may be rehydrated and used as a complete medium, or may be incorporated into other media" for the cultivation of anaerobes and lactic acid bacteria, and for the identification of bacteria on the basis of their ability to coagulate or peptonize milk. In another example, on page 161, the BBL Manual of Products and Laboratory Procedures teaches a "Milk-Protein Hydrolysate", which is used for general bacteriological culture work. Moreover, its nutritive value is described as "excellent because of the comprehensive amino acid content". Moreover, Fassolitis teaches a method for the cultivation and/or growth of eukaryotic cells, *i.e.*, epithelial cells, using a powdered nonfat dry skim milk filtrate (NDMF) as an eukaryotic cell culture medium supplement. *See* page 201, Column 1, under "Preparation of milk fraction", wherein Fassolitis teaches a method of making NDMF comprising reconstituting a dry milk powder product. On page 200, Column 2, under "Cell culture medium", Fassolitis teaches a cell culture medium supplemented with 5% NDMF, and adjusted to a pH of 6.8 to 7.4 that is used to propagate epithelial cells (*see* Table 1 on page 201). Thus, as evidenced by BBL Manual of Products and Laboratory Procedures and Fassolitis, one of ordinary skill in the art would indeed regard the prior art dry powdered milk and milk products taught by Peebles and Getler as agglomerated eukaryotic cell culture medium powders and eukaryotic cell culture medium supplement powders, which are able to support the cultivation

and/or growth of eukaryotic cells, contrary to the assertion of Applicant, because the prior art references of Peebles and Getler clearly teach agglomerated eukaryotic cell culture media comprising the requisite components necessary for the cultivation and/or growth of eukaryotic cells.

Finally, it is noted that the references do not teach that the compositions can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference compositions. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

Therefore, each of the cited references of Peebles and Getler is deemed to anticipate the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 27, 36, 39, 70, 72, 92-95 and 103-105 as amended remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Peebles (A) and Getler et al. (N) in view of DiSorbo et al. (AG2). The rejection stands for the reasons set forth in the previous office action and set forth below.

Applicant's arguments have been fully considered but they are not deemed persuasive because the cited references provide the suggestions and motivation to the claimed invention.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the primary references of Peebles and Getler were relied upon for the reasons set forth immediately above. Neither Peebles nor Getler teach a kit for use in the cultivation of a cell, therefore the secondary reference of DiSorbo was relied upon because DiSorbo teaches a kit comprising one or more containers containing nutritive media, media supplements and media subgroups and one or more containers containing solvents, which can be used to formulate a medium to support the in vitro cultivation of a cell, e.g., bacterial cell, a fungal cell, a plant cell, or an animal cell.

Thus, with Peebles and Getler providing the claimed agglomerated eukaryotic cell culture medium powders, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the referenced powders in the making of a kit by containing the referenced powders in a first container and providing one or more additional containers containing one or more solvents because DiSorbo teaches a kit comprising one or more containers containing nutritive media, media supplements and media subgroups and one or more containers containing solvents, which can be used to formulate a medium to support the in vitro cultivation of a cell, e.g., bacterial cell, a fungal cell, a plant cell, or an animal cell. One of ordinary skill in the art would have been motivated to combine the instantly claimed materials in the making of a kit for use in the cultivation of a cell because one would have had a reasonable expectation of success that the making of the claimed kit as a product of sale would be useful and convenient to the biomedical community because DiSorbo relates the reduced cost that his invention provides for the preparation of cell culture media, since the media subgroupings can be easily stored and admixed to make custom media, when needed. Therefore, the invention as a whole was clearly *prima facie* obvious in the absence to the contrary.

Allowable Subject Matter

3. Claims 44-46 are allowable.

Conclusion

4. This is a request for continued examination of Applicant's earlier Application No. 09/606,614. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

MCF

October 1, 2003

CHRISTOPHER R. TATE
PRIMARY EXAMINER